ASTM International Committee E56 on Nanotechnology

Standards Update for 2013

E56 on Nanotechnology



http://www.astm.org/COMMIT/COMMITTEE/E56.htm

Debra L. Kaiser Material Measurement Laboratory, NIST Chair, Committee E56

Next Meeting: May 5-6, 2014, Toronto, Canada

ANSI–Nanotechnology Standards Panel Webinar December 5, 2013





ASTM E56

Overview

- Established in 2005
- Membership: 171 individuals and organizations
- 22 countries represented in membership
- Committee meets twice yearly (May and November)
- Focus is on standards for measurements of nanomaterials

Scope

- Develop standards and guidance for nanotechnology and nanomaterials
- Coordinate with existing ASTM standardization efforts of other ASTM committees as they relate to nanotechnology
- Maintain appropriate global liaison relationships with activities (internal and external) related to this subject area
- Participate in the development of symposia, workshops, and other related activities to enhance the development of standards



E56 Organization

Chair: Debra Kaiser (NIST)

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Vice-Chair: Stacey Harper (Oregon State)

ASTM Staff Manager: Kate McClung

Membership Secretary: Tony Thornton (Micromeritics)

Secretary: Aleksandr Stefaniak (NIOSH)

Technical Subcommittees

E56.01

Informatics and Terminology E56.02

Physical and Chemical Characterization

E56.03

Environment, Health, and Safety E56.06

Nano-enabled Consumer Products

E56.90

Executive

E56.04

Intellectual Property Issues

E56.05

Liaison and International Cooperation

E56.91

Strategic Planning and Review

Advisory Subcommittees



Types of ASTM Standards

- Terminology standard: a document composed of definitions of terms; explanations of symbols, abbreviations, or acronyms (1)*
- Guide: a compendium of information or series of options that does not recommend a specific course of action (6)
- Practice: a definitive set of instructions for performing one or more specific operations that
 does not produce a test result (1)
- Test method: a definitive procedure that produces a test result; requires an interlaboratory study (4)
- Specification: an explicit set of requirements to be satisfied by a material, product, system, or service
- Classification: a systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics such as origin, composition, properties, or use
- Interlaboratory study: conducted to develop precision and bias statements
 - Precision: closeness of agreement between test results obtained under prescribed conditions; includes repeatability and reproducibility standard deviations
 - Bias: systematic error that contributes to the difference between the mean of a large number of test results and an accepted reference value

^{*} Denotes number of E56 published standards of that type



New Published Standards and Reapproved Standards in 2013

Subcommittee E56.01: Informatics and Terminology

 E909-13 Standard Guide for Investigation/Study/Assay Tab-Delimited Format for Nanotechnologies (ISA-TAB-Nano): Standard File Format for the Submission and Exchange of Data on Nanomaterials and Characterizations

Subcommittee E56.02: Physical and Chemical Characterization

• E2864-13 Standard Test Method for Measurement of Airborne Metal and Metal Oxide Nanoparticle Surface Area Concentration in Inhalation Exposure Chambers Using Krypton Gas Adsorption

Subcommittee E56.03: Environment, Health, and Safety

- E2535-07 (2013) Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings
- E2524-08 (2013) Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
- E2525-08 (2013) Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
- E2526-08 (2013) Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells



Proposed New Standards

Subcommittee E56.02: Physical and Chemical Characterization

 WK39049 New Guide for Sample Preparation of Charge-Stabilized Metal Nanoparticles for Electron Microscopy*

Subcommittee E56.03: Environment, Health, and Safety

- WK34427 New Guide for Nanotechnology Environment, Health, and Safety (EHS) Education and Training
- WK38731 New Specification for ASTM Nanotechnology Environment, Health and Safety Personnel Certification Program

Subcommittee E56.06: Nano-Enabled Consumer Products

 WK37636 New Guide for Detection and Characterization of Manufactured Silver Nanomaterials in Textiles*

Subcommittee E56.91: Strategic Planning and Review

• **WK37514** New Guide for E56 and F04 Workshop on Nanomaterials in Medicine: Research, Applications, Products, and Risk

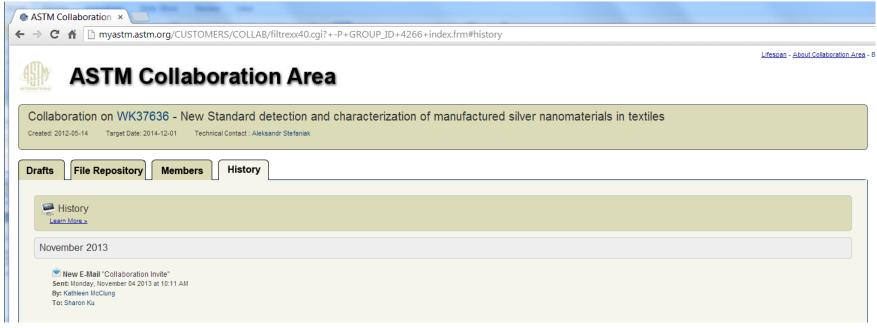
*Collaboration area on ASTM website



Collaboration Areas

- Established as an interactive web tool to facilitate:
 - Development of new standards and review of existing standards
 - Discussions on specific topics related to standards
- Leader invites E56 members to join a collaboration area; members can also request to join

Example of a collaboration area website for development of a new standard



- Collaboration area includes drafts of standard, relevant files, list of members, history of member comments and actions
- Members can post new documents and comments on the area



ASTM E56 Fall 2013 Meeting

- FDA requested that E56 hold its Fall meeting at the FDA White Oaks Campus in Silver Spring, MD (May 2013)
- ASTM E56 Executive Committee approved the request
- Meeting held on October 30-31 with webinar capability for the entire meeting
- Agenda
 - FDA Welcome and Opening Presentations (Carlos Pena and Subhas Malghan)
 - Regular business meetings of all Subcommittees
 - FDA Nanotechnology Laboratory Tours
 - Guest speakers:
 - Heather Benko, ANSI: "Update on ISO TC229" and "ANSI-NSP Nanotechnology Standards Database"
 - Stephen Freiman, Freiman Consulting: "A Uniform Description System for Nanomaterials"
 - Connor Stone, Ohio State Univ.: "Challenges of Standards Development for Nanotechnology"
 - Alan Kennedy and Jessica Coleman, USACE ERD: "Program on Developing Protocols for Nanomaterials"
 - Ajit Jilla, NIST: "Patents and Intellectual Property Management in Nanotechnology Standardization: A NIST Perspective"
- 16 FDA participants in person
- Planning to hold a future E56 meeting at FDA, likely in Spring 2015

